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~~\*\*Diplomates, American Board of Neurological Surgery~~

December 2, 1999

Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fisher's Lane RM 1061  
Rockville, Maryland 20852

Dear Sirs:

My comments are in reference to docket number 97N-484S.

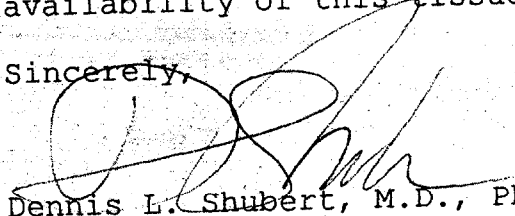
As a neurosurgeon who cares for spine problems among other problems; I often use allograft bone tissue.

As I am sure you are aware, the Food and Drug Administration regulates the preparation process of this tissue and literature would suggest that the safety of using allograft is "excellent." Presently my hospital obtains its allograft from reputable suppliers and all tissue is tracked through the blood bank as required by regulation.

I personally see nothing to be gained by any additional regulation of this tissue, particularly in the realm of medical device.

Allograft tissue has become standard procedure and in just my corner of the world approximately five hundred patient's a year are saved considerable pain and time out of work because of the availability of this tissue.

Sincerely,

  
Dennis L. Shubert, M.D., Ph.D.

DLS/gjh R: 12/02/99 T: 12/02/99

97N-484S

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